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09/846,347	04/30/2001	George Jackowski	2132.032	3155

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EXAMINER
CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
1641	13

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,347	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *3-9 and 29-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2 and 10-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 10-28, drawn to biopolymer markers, classified in class 436, subclass 512.

II. Claims 3-9, drawn to a method for evidencing and categorizing at least one disease state, classified in class 435, subclass 69.2.

III. Claims 29-32, drawn to a diagnostic assay kit for determining the presence of the biopolymer markers or analytes, classified in class 436, subclass 86.

IV. Claims 33-35, drawn to a process for identifying therapeutic avenues related to a disease, classified in class 422, subclass 119.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and (II, IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products from invention I, can be practiced with another materially different process other than inventions II and IV, such as isolation and separation of the specific analytes.

3. Similarly, inventions III and (II, IV) are also related as product and process of use. Likewise, invention III can be practiced by materially different process other than inventions II and IV, such as isolation and separation.

4. Inventions I and III are patentably distinct and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I is directed to biompolymers consisting of specific polypeptides, whereas invention III is directed to polyclonal antibodies produced against the polypeptide

markers. Both polypeptides and antibodies are patentably distinct in terms of structure and functions. Therefore, inventions I and III are distinct and unrelated inventions.

5. Inventions II and IV are patentably distinct and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention II and IV are distinct and unrelated inventions. The feature of conducting mass spectrometric analysis and correlation of isolated biopolymer markers with normal and patients in invention II, is not required by the claims of invention IV. The feature of using biopolmer markers and its variants or moieties as direct therapeutic modalities, either alone or in conjunction with an effective amount of a pharmaceutically effective carrier in invention IV, is not required by the claims of invention II.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for the other, therefore restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Mr. Landers on April 14, a provisional election was made without traverse to prosecute the invention of group I, claims 1-2, 10-28. Affirmation of this election must be made by applicant in replying to this Office action. Claim3-9, 29-32 and 33-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-2, 10-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, "indicating at least one particular disease" is vague and indefinite. It is unclear what particular disease applicant refers to. Clarification is needed.

Similarly, claim 18 shares the same problem as claim 1.

With respect to claim 10, line 2 and 5, "analyte thereof" is vague and confusing. It is unclear what analyte applicant refers to, i.e. what type of analyte for a specified amino acid.

Similarly, claims 18 and 25 share the same problem as claim 10.

With respect to claim 15, "wherein the sample" lacks antecedent basis.

With respect claim 16, "wherein said sample" lacks antecedent basis.

With respect to claim 17, "wherein said marker" is vague and indefinite. It is suggested that applicant changes "marker" to "biopolymer marker" for consistence. Similarly, claim 18 shares the same problem as claim 17.

With respect to claim 17, line 3, "specific therefor" is vague and confusing. It is suggested that applicant changes "therefor" to "thereof" for clarification.

Claim 25 shares the same problem as claim 17.

With respect to claim 18, line 2, "therapeutic avenues related to a disease state" is vague and indefinite. It is unclear what disease applicant refers to. It is not clear what "therapeutic avenues" applicant refers to.

Claims 26 and 27 share the same problem as claim 18.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-2 are rejected under 35 U.S.C. 102 (a) as being anticipated by Bar-Or et al. (A) (WO200125265)

Bar-Or et al. reference is an invention relates to a metal binding peptides that prevent damage by reactive oxygen. Bar-Or et al. teach a sequence of polypeptides comprising the instant SEQ ID No. 1 as a reactive species inhibitory peptide. (Example 10, page 43)

Claim 2 is rejected because it is an improper dependent claim and the intended use, i.e. congestive heart failure, is not given patentable weight.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-2, 10-14, 17-22, 25-26 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bar-Or et al.(B)(WO000020840)

With respect to claim 1, Bar-Or et al. teach a rapid methods for the detection of ischemic states and kits for use in such method. Bar-Or et al. teach a sequence of polypeptides comprising of the instant SEQ ID. No.1 as the measurement of an ischemic event. (See Example 32, page 60)

Claim 2 is rejected because it is an improper dependent claim and the intended use, i.e. congestive heart failure, is not given patentable weight.

Bar-Or et al. also teach a diagnostic assay kit comprising the instant SEQ ID No. 1 as the binding partner to detect ischemic event for clinical monitoring purposes. (Figure 3, claims 47-56, page 19, line 25- page 22, line 3) Bar-Or et al. teach using conventional ELISA, sandwich assay, Mass Spectrometry or Spectrophotometric analysis as the detecting means to determine the binding level from patient's serum or plasma sample. (See supra; Example 13-17; claim 11) Bar-Or et al. teach immobilized monoclonal antibodies, i.e. sequence specific for N-terminus polypeptide (as the instant recited SEQ ID. No.1) on a solid support. (claim 56) Although Bar-Or et al. do not specifically teach using a labeled antibody. It is inherent a contemplation ordinary in the art of immunoassay, including sandwich, ELISA or enzyme assay. (See page 19, line 25-page 21, line 30)

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 15,16, 23, 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Or et al. (B) in view of Hutchens et al. (USP 6225047).

Bar-Or et al references have been discussed but does not explicitly teach obtaining the patient sample in an unfractionated body fluid, a tissue sample or nature body fluids. (Note, Bar-Or et al teach "fractionating" samples, i.e. serum or plasma, supra) Hutchens et al. disclose a method and kit for identifying biopolymer markers (diagnostic markers) representative of or capable of categorizing specific disease states using Surface Enhanced Laser Desorption Ionization Spectrometry Mass Spectrometry (SELDI-MS). Hutchens et al teach that the sample choice could be from unfractionated body fluid such as blood, urine, blood products, or tissue sample. The method and kit may be applied to multiple samples at different times (see column 8, lines 45-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to make a diagnostic assay kit in combination of the teaching of Bar-Or et al., i.e. SEQ ID NO. 1 which comprises a biopolymer used as a diagnostic marker of a disease state, e.g. ischemic event, with the range of sample choice of as taught by since economy of convenience is a routine practice in the clinical practice. (Col. 7, line 32-40)

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641

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April 22, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
05/04/03